



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Thomas M. DiMauro, Mohamed Attawia, Hassan Serhan, Melissa Grace, Michael Slivka, Thomas G. Ferro, Vivek N. Shenoy, Alonso D. Cook, and Scott Bruder

Application No.: 10/723,250 Group Art Unit: 1617

Filed: November 26, 2003 Examiner: Williams, Leonard M.

Confirmation No.: 6059

Title: LOCAL INTRAOSSSEOUS ADMINISTRATION OF BONE FORMING AGENTS AND ANTI-RESORPTIVE AGENTS, AND DEVICES THEREFOR

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
March 23, 2006	Signature
Date	Linda M. Byrnes
Typed or printed name of person signing certificate	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:

a Statement under 37 CFR 1.97(e), as checked below, or

a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:

a Statement under 37 CFR 1.97(e), as checked below, and

a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

Copies of the cited references are enclosed. [B9-B19 and C43-C116]

Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.

Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]

The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:

the explanation provided on the attached sheet.

the explanation provided in the Specification.

submission of the enclosed International Search Report.

submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

the enclosed English language abstract.

Applicant requests that the following non-published pending applications be considered:
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

____ Examiner

____ Date

A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.

A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated:

March 23, 2006

PTO-1449 REPRODUCED

SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION

March 20, 2006

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
3518.1024-000APPLICATION NO.
10/723,250FIRST NAMED INVENTOR
Thomas M. DiMauroFILING DATE
November 26, 2003EXAMINER
Williams, Leonard M.CONFIRMATION NO.
6059GROUP
1617

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A21	4,427,649	01-24-1984	Dingle, <i>et al.</i>
	A22	5,095,037	03-10-1992	Iwamitsu, <i>et al.</i>
	A23	5,368,841	11-29-1994	Trauner, <i>et al.</i>
	A24	5,656,272	08-12-1997	Le, <i>et al.</i>
	A25	5,833,984	11-10-1998	Eibl, <i>et al.</i>
	A26	6,284,471	09-04-2001	Le, <i>et al.</i>
	A27	6,294,170	09-25-2001	Boone, <i>et al.</i>
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	A29	6,340,369 B1	01-22-2002	Ferree
	A30	6,713,246	03-30-2004	Reinecke, <i>et al.</i>
	A31	US 2001/0006948	07-05-2001	Kang, <i>et al.</i>
	A32	US 2001/0016195 A1	07-05-2001	Tobinick
	A33	US 2001/0026801	10-04-2001	Tobinick
	A34	US 2002/0026244 A1	02-28-2002	Trieu
	A35	US 2002/0032155 A1	03-14-2002	Ferree
	A36	US 2002/0198599 A1	08-08-2002	Chang, <i>et al.</i>
	A37	US 2003/0049256 A1	03-13-2003	Tobinick
	A38	US 2003/0134792 A1	07-17-2003	Pike, <i>et al.</i>
	A39	US 2004/0193274 A1	09-30-2004	Trieu
	A40	US 2004/0229786 A1	11-18-2004	Attawia, <i>et al.</i>
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	A43	6,352,557 B1	03-05-2002	Ferree
	A44	6,419,944	07-16-2002	Tobinick

EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED " SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION	ATTORNEY DOCKET NO. 3518.1024-000	APPLICATION NO. 10/723,250
March 20, 2006	FIRST NAMED INVENTOR Thomas M. DiMauro	FILING DATE November 26, 2003
(Use several sheets if necessary)	EXAMINER Williams, Leonard M.	CONFIRMATION NO. 6059
		GROUP 1617

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C43	Abstracts of the North American Spine Society 17 Annual Meeting, Montreal, Canada, October 29 through November 2, 2002, <i>The Spine Journal</i> 2(5 Suppl):49S-50S (2002).
C44	Ahn, N. U., <i>et al.</i> , "Effect of Nutrient Concentration and OP-1 on the Metabolism of Intervertebral Disc: <i>In Vitro</i> Organ Culture Study," 28, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine, Vancouver, Canada (May 2003).
C45	Alini, M., <i>et al.</i> , "A Biological Approach in Treating Disc Degeneration: Not for Today, but Maybe for Tomorrow," <i>European Spine Journal</i> , 11(Suppl 2):S215-S220 (2002).
C46	Andonopoulos, A. P., <i>et al.</i> , "Intra-articular Anti-Tumor Necrosis Factor α Antibody in Recalcitrant Arthritis of Behcet's Disease," <i>Clinical and Experimental Rheumatology</i> 21(4 Suppl 30):S-57-S58 (July-August 2003).
C47	Aoki, Y., <i>et al.</i> , "Local Application of Disc-Related Cytokines on Spinal Nerve Roots," <i>Spine</i> 27(15): 1614-1617 (2002).
C48	Arai, I., <i>et al.</i> , "Pretreatment with Loxoprofen Sodium, 6-OHDA or Anti TNF-Alpha Antibody Reduce Fos-Like Immunoreactivity in Rat Experimental Lumbar Disc Herniation," 111, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C49	Ariga, K., <i>et al.</i> , "Mechanical Stress-Induced Apoptosis of Endplate Chondrocytes in Organ-Cultured Mouse Intervertebral Discs," <i>Spine</i> , 28(14):1528-1533 (2003).
C50	Bokarewa, M., and Tarkowski, A., "Local Infusion of Infliximab for the Treatment of Acute Joint Inflammation," <i>Ann. Rheum. Dis.</i> , downloaded from ard.bmjjournals.com on 30 November 2005, www.annrheumdis.com 62:783-784 (2003).
C51	Braun, J. and Sieper, J., "Overview of The Use of The Anti-TNF Agent Infliximab in Chronic Inflammatory Diseases," <i>Expert Opin. Biol. Ther.</i> 3(1):141-168 (2003).
C52	Braun, J., <i>et al.</i> , "Anti-Tumour Necrosis Factor α Therapy for Ankylosing Spondylitis: International Experience," <i>Ann. Rheum. Dis.</i> , 61(Supp. III):iii51-iii60 (2002).

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C53	Bringman, T.S., <i>et al.</i> , "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Application for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> , 6(5):489-507 (1987).
C54	Brown, K., <i>et al.</i> , "Gelatin/Chondroitin 6-Sulfate Microspheres for the Delivery of Therapeutic Proteins to the Joint," <i>Arthritis. & Rheum.</i> , 41(12):2185-2195 (1998).
C55	Burke, J. G., <i>et al.</i> , "Human Nucleus Pulposus Secretes Transforming Growth Factor Beta-1 and Basic Fibroblast Growth Factor," <i>189, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C56	Burke, J.G., <i>et al.</i> , "Intervertebral Discs Which Cause Low Back Pain Secrete High Levels of Proinflammatory Mediators," <i>J. Bone Joint Surg. [Br]</i> , 84-B, 196-201 (2002).
C57	Cardone, D.A., and Tallia, A.F., "Diagnostic and Therapeutic Injection of the Hip and Knee," <i>Am. Fam. Physician</i> , 67(10):2147-2152 (2003).
C58	Connolly, J., <i>et al.</i> , "Development of an Osteogenic Bone-Marrow Preparation," <i>J. of Bone and Joint Surgery, Inc.</i> , 71-A (5):684-691 (1989).
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C60	Cornefjord, M., <i>et al.</i> , "Cerebrospinal Fluid Biomarkers in Experimental Spinal Nerve Root Injury," <i>38, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C61	Dayer, J.M., "The Pivotal Role of Interleukin-1 in the Clinical Manifestations of Rheumatoid Arthritis," <i>Rheumatology, Oxford University Press, London, GB</i> , 42(Suppl 2):ii3-ii10 (2003).
C62	Diwan, A.D., <i>et al.</i> , "Current Concepts in Intervertebral Disk Restoration," <i>Tissue Engineering in Orthopedic Surgery</i> , 31(3):453-464 (2000).

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C63	Edwards, S. L., <i>et al.</i> , "Radiographic Assessment of Posterolateral Spine Fusion With and Without Platelet Rich Plasma," <i>117, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C64	Eustice, Carol & Richard, "What is Viscosupplementation?" http://arthritis.com/od/kneetreatments/g/viscosupplement_p.htm , 12/9/05.
C65	Frain, J., <i>et al.</i> , "Use of cDNA Microarrays to Investigate Cytokine Expression in Intervertebral Disc Degeneration," <i>126, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C66	Gabay, C., "IL-1 Trap," <i>Curr. Opin. Invest. Drugs, Curr. Drugs, London, GB</i> , 4(5):593-597 (2003).
C67	Ganey, T.M., and Meisel, H.J., "A Potential Role for Cell-Based Therapeutics in the Treatment of Intervertebral Disc Herniation," <i>Eur. Spine J.</i> , 11 (Suppl. 2): S206-S214 (2002).
C68	Gordon, J.L., <i>et al.</i> , "Metalloproteinase Inhibitors as Therapeutics," <i>Clin. Exp. Rheumatol.</i> , 11(Suppl. 8): S91-S94 (1993).
C69	Goupille, P., <i>et al.</i> , "Matrix Metalloproteinases: The Clue to Intervertebral Disc Degeneration?," <i>Spine</i> , 23(14): 1612-1626 (1998).
C70	Kawakami, M., <i>et al.</i> , "Role of IL-8, MCP-1 and PH in Neuropathic Pain Enhanced by Degenerative Nucleus Pulposus," <i>127, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C71	Hunter, C. J., <i>et al.</i> , "Functional Behavior of Notochordal Cell Clusters in the Canine Nucleus Pulposus: Cell Communication and Survival," <i>70, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C72	Igarashi, A., <i>et al.</i> , "Inflammatory Cytokines Release From Facet Joint Tissue in Degenerative Lumbar Disorders," <i>262, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).

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C73	Imai, Y., <i>et al.</i> , "Effect of Recombinant Human Osteogenic Protein-1 on Extracellular Matrix Metabolism by Human Annulus Fibrosus and Nucleus Pulposus Cells," 205, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C74	Imai, Y., <i>et al.</i> , "The Quantification of Cytokine-Induced Matrix Catabolism in Tissue Engineered Intervertebral Discs," 67, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C75	Inui, Y., <i>et al.</i> , "Fas-Ligand Expression on Nucleus Pulposus Cells Begins in Developing Embryo," 42, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C76	Johnson, W.H., <i>et al.</i> , "Collagenase Inhibitors: Their Design and Potential Therapeutic Use," <i>J. Enzyme Inhib.</i> , 2:1-22 (1987).
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C78	Kato, H., <i>et al.</i> , "The Effect of IL-1 on the Rabbit Intervertebral Disc In Vivo," 199, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C79	Kawakami, M., <i>et al.</i> , "Possible Mechanism of Painful Radiculopathy in Lumbar Disc Herniation," <i>Clin. Orthop.</i> , 351:241-251(1998).
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C81	Ohtori, S., <i>et al.</i> , "TNF- α Deficient Mice Have Fewer Macrophages in Injured Nerve and Reduced Glial Activation in DRG and Spinal Cord," 250, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).

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C82	Korhonen, T., <i>et al.</i> , "Efficacy of Infliximab for Disc Herniation-Induced Sciatica One-Year Follow-Up," 14, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C83	Kwon, U-H., <i>et al.</i> , "Dexamethsone Stimulates Cellular Proliferation While Downregulates Matrix Synthesis in Intervertebral Disc Cells," 29, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C84	Lane, N.E. <i>et al.</i> , "Basic Fibroblast Growth Factor Forms New Trabeculae That Physically Connect With Pre-Existing Trabeculae, and This New Bone is Maintained With an Anti-Resorptive Agent and Enhanced With an Anabolic Agent in an Osteopenic Rat Model," <i>Osteoporos. Int.</i> , 14:374-382 (2003).
C85	LaVan, D. A., <i>et al.</i> , "Small-scale Systems for <i>in vivo</i> Drug Delivery," <i>Nature, Biotechnology</i> , 21(10):1184-1191 (2003).
C86	Lee, C. S., <i>et al.</i> , "A Single Period of Hyperphysiologic Stretch Induces IL-6, TGF-beta and Cell Proliferation in Anulus Fibrosus Cells," 215, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C87	Lehman, T. J. A., <i>et al.</i> , "Thalidomide Therapy for Recalcitrant Systemic Onset Juvenile Rheumatoid Arthritis," <i>J. Pediatrics</i> , 140(1):125-127 (2002).
C88	Le Maitre, C. L., <i>et al.</i> , "Expression of the IL-1 Family in Human Intervertebral Disc," 217, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C89	Le Maitre, C. L., <i>et al.</i> , "Response of Human Intervertebral Disc Cells to IL-1," 216, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C90	Le Visage, C., <i>et al.</i> , "Interaction of Human Mesenchymal Stem Cells with Disc Cells: Changes in Biosynthesis of Extracellular Matrix," 25, <i>Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).

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C91	Li, J., <i>et al.</i> , "The Effects of Bone Morphogenetic Protein 2 (BMP-2) and Cartilage-Derived Morphogenetic Protein 2 (CDMP-2) on Aggrecan Gene Expression in Chondrocytes," <i>30, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C92	Liang, C.-M., <i>et al.</i> , "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," <i>Biochem. Biophys. Res. Comm.</i> 137 (2):847-854 (1986).
C93	Lotz, J. C., <i>et al.</i> , "Cytokines in Normal, Degenerated, and Nucleoplasty-Treated Porcine Discs," <i>157, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C94	Maeda, S. and Kokubun, S., "Changes With Age in Proteoglycan Synthesis in Cells Cultured <i>In Vitro</i> From the Inner and Outer Rabbit Annulus Fibrosus," <i>Spine</i> , 25(2):166-169 (2000).
C95	Meijer, H., <i>et al.</i> , "The Production of Anti-Inflammatory Cytokines in Whole Blood by Physico-Chemical Induction," <i>Inflamm. Res.</i> , 52: 404-407 (2003).
C96	Miyamoto, H., <i>et al.</i> , "The Effect of Mechanical Stress on the Production of Inflammatory Agents by Disc Cells," <i>110, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C97	Sakai, D., <i>et al.</i> , "Autologous Transplantation of Mesenchymal Stem Cells for Disc Repair," <i>24, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
C98	Molloy, T., <i>et al.</i> , "The Roles of Growth Factors in Tendon and Ligament Healing," <i>Sports Med.</i> , 33(5): pp.381-394 (2003).
C99	Nikas, S. N., <i>et al.</i> , "Treatment of Resistant Rheumatoid Arthritis by Intra-Articular Infliximab Injections: A Pilot Study," <i>Ann. Rheum. Dis.</i> , downloaded from ard.bmjjournals.com on 2 November 2005, www.annrheumdis.com 63: 102-103 (2004).

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C100	Ohtori, S., <i>et al.</i> , "TNF- α and TNF- α Receptor 1 Upregulation in GLIA and Neurons After Nerve Injury. Studies in Murine DRG and Spinal Cord," <i>13, Abstracts of the 30th Annual Meeting of the International Society for the Study of the Lumbar Spine</i> , Vancouver, Canada (May 2003).
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PTO-1449 REPRODUCED SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION March 20, 2006 (Use several sheets if necessary)		ATTORNEY DOCKET NO. 3518.1024-000	APPLICATION NO. 10/723,250
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		EXAMINER Williams, Leonard M.	CONFIRMATION NO. 6059
			GROUP 1617

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